IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s): Vilsmeier et al.
Serial No.: 10/634,133
Filed: August 4, 2003

Title: PATIENT POSITIONING SYSTEM FOR

RADIOTHERAPY/RADIOSURGERY BASED ON MAGNETICALLY

TRACKING AN IMPLANT

Examiner: Nasir Shahrestani

Art Unit: 3737

Docket No. SCHWP0185USA

REPLY TO EXAMINER'S ANSWER

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The following comments are presented in response to the various contentions of the Examiner set forth in the Examiner's Answer.

Claim 1

In response to Appellants' arguments that a *prima facie* case of obviousness has not been established, the Examiner provides the following comments.

Initially, Appellant had alleged that the prior art references of record do not teach or fairly suggest" determining a position of the at least one implant based on the detected emission and determining a current position of the target volume based on the determined position of the at least one implant" as required by the claim language. The Cosman reference has provided clear teachings with respect to positional referencing of markers, subsequent to stimulation, and determination of a position of a target

volume based on the determined position of the markers (abstract). Absent from the Cosman reference, as stated in the final rejection, is a teaching of marker implants and the inductive stimulation of such. The Whitehurst et al. reference was applied to cure the deficiencies within Cosman, providing a clear teaching of numerous implants (fig. 6) that are inductively stimulated and positionally referenced with respect to the stimulator and each-other.

The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there *must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*" *KSR*, 550 U.S. at ____, 82 USPQ2d at 1396 (emphasis added). As will be shown below, the Examiner has not provided any articulated reasoning that supports the legal conclusion of obviousness, nor is it readily apparent why or how one would modify *Cosman* based on Whitehurst as alleged by the Examiner.

In the rejecting claim 1, the Examiner, citing to col. 3, Ins. 29-36, states *Cosman* references markers in the vicinity of the target volume.² The cited portion of *Cosman* is reproduced below.

Basically, scan data is stored to specify the location of a target in a patient's body, generally defined in three-dimensional scan space (as slice data) with respect to references. The scan data is stored in a treatment processing system T which receives further data from a camera system C. Specifically the camera system C senses the instant position of the patient P and the beam B (in camera space) on the basis of marker locations on the patient P and the machine L.

² See pages 2-3 of the final Office Action

¹ Page 6 of the Examiner's answer

From the cited passage, it is clear the markers identified in *Cosman* are optical markers, e.g., light emitting or light reflecting markers that are detectable by a camera of a tracking system.

Moving now to *Whitehurst*, the Examiner relies on Fig. 6 (inductive coil 146) as inductively stimulating an implant, and proposes to combine this teaching with *Cosman*. As discussed in the Appeal Brief, the device of *Whitehurst* is an implantable stimulator, the purpose of which is to deliver an electrical stimulation and/or a drug to a patient. *Whitehurst* is silent with respect to this stimulator being used to determine a position.

Looking at the two references, *Cosman* discloses the *optical markers* can be used to detect a position (e.g., via a camera system). As disclosed in *Cosman*, a camera system determines a position of the patient based on the markers. Such camera systems generally require a line of site between the camera and the markers in order to detect the emitted or reflected light from the markers. In contrast to the markers of *Cosman*, *Whitehurst* does not disclose that the implant can be used to detect a position, nor has *Whitehurst* been found to teach detection of an emission from the inductively stimulated implant. Thus, on their face the references provide no reasonable basis to modify *Cosman's* optical markers based on the *Whitehurst's* inductive implant so as to inductively stimulate the markers to detect a position as alleged by the Examiner.

Moreover, the Examiner provides no rationale with respect to how or why one having ordinary skill in the art would modify *Cosman's* optical markers, which are used to determine a position, so as to use *Whitehurst's* inductive implant, which is used to stimulate a patient, to determine a position of the implant based on a detected emission

from the inductively stimulated implant. In other words, the Examiner has not provided some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Accordingly, a prima facie case of obviousness has not been established for claim 1.

In response to Appellants' arguments that the references do not determine a position of the implant based on the detected emission, the Examiner provides the following comments.

Secondly, Appellant has stated that the Whitehurst reference discloses that the stimulator may be inductively stimulated, for purposes of powering the device and to communicate data to/from the simulator. Appellant has argued that Whitehurst is silent with respect to determining a position of the stimulator based on the detected emissions from the stimulator. Examiner respectfully highlights the fact that the Whitehurst reference was applied as a reference which teaches inductive stimulation of implants, thus providing a confirmation of their location with respect to the stimulator as well as one-another. The current claim has no language which necessitates the determination of the position of the stimulator.³

Regarding the Examiner's remarks with respect to the claims not reciting a stimulator, it is noted that *Whitehurst* refers to the implant as a stimulator (see, e.g., Abstract), and Appellants were using *Whitehurst's* terms in discussing this reference. Regarding the Examiner's comment that *Whitehurst* teaches inductive stimulation of implants, thus providing a confirmation of their location with respect to the stimulator, the undersigned has searched the disclosure of *Whitehurst* and has found no such teaching.⁴

³ Page 7 of the Examiner's answer

⁴ A word search was performed for the words "position" and "location", and any instance of these words was not found to be related to determining a position/location of the implant relative to the inductive stimulator

Inductive stimulation of the implant, as taught in *Whitehurst*, is for powering the device or transferring data to/from the device, and not for detecting a position. Thus, modifying *Cosman* based on *Whitehurst* does not result in determining a position of the implant based on a detected emission from the implant.

Claim 3

In response to Appellants' arguments that the Examiner has not shown that the references teach "generating a dynamic electromagnetic field in the vicinity of but outside the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially reemits the absorbed energy", the Examiner provides the following comments.

Furthemore on page 13, Appellant has alleged that absence, from the Cosman reference, the generation of a dynamic electromagnetic field in the vicinity of but outside the patient, wherein the at least one implant inductively absorbs energy via the electromagnetic field and the at least one implant at least partially re emits the absorbed energy. Examiner respectfully points out that Cosman teaches all the above stated limitations with the exception of inductive stimulation of implants, a deficiency made obvious by the teachings of Whitehurst.⁵

After pointing out that the Examiner has not shown the above-quoted feature of claim 3, the Examiner responds by making the conclusory statement that Cosman teaches all the claimed features except for inductive stimulation. In other words, the Examiner contends that the above feature is disclosed in *Cosman*. Other than making the conclusory statement, however, the Examiner provides no indication where such features may be found.

 $^{^{\}rm 5}$ Page 7 of the Examiner's answer

As noted above, "rejections on obviousness *cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at _____, 82 USPQ2d at 1396 (emphasis added). The rejection of claim 3 is premised on a conclusory statement, without any support for this statement. Clearly, such rejection is improper.

Accordingly, reversal of the rejection of claim 3 is respectfully requested.

Claim 4

In addressing Appellants' arguments that the Examiner has not established a prima facie case of obviousness for claim 4, the Examiner provides the following comments.

With respect to claim 4, appellant argues that knowledge of inner organs is not taught within the claimed language. Examiner respectfully disagrees and maintains that a user, or one skilled in the art carrying out the procedures of the prior art references, has a broad knowledge of inner organs.⁶

It is first noted that Appellants were not arguing that "knowledge on inner organs is not taught in the claims", but that the Examiner has not shown each and every feature of claim 4 in the cited art and, thus, has not established a *prima facie* case of obviousness. Appellants acknowledge that the position of the inner organs is generally known by those having ordinary skill in the art. However, claim 4 requires more than simply knowledge of the position of the inner organs. The Examiner simply has not shown that the cited art teaches determining a current position of the target volume

⁶ Page 7 of the Examiner's answer

based on the determined position of the at least one implant and knowledge of the position of the patient's inner organs relative to the at least one implant.

Accordingly, reversal of the rejection of claim 4 is respectfully requested.

Claim 8

In addressing Appellants' arguments that a *prima facie* case of obviousness has not been established for claim 8, the Examiner provides the following comments.

With respect to claim 8, it is clearly taught that a procedure/therapy is carried out based on received data. Hence, therapy is activated only when a target is within a desired/predetermined range.

As pointed out in the Appeal Brief, the Examiner has not shown that *Cosman* or *Whitehurst* teaches activating the therapy device only when the position of the target volume is within a predetermined range about a current target point of the therapy device. Instead of further elaborating on this deficiency, the Examiner simply makes the conclusory statement that the features are taught in *Cosman*. Thus, the Examiner has not shown where *Cosman* or *Whitehurst* teach the claimed features and, thus, has not established a *prima facie* case of obviousness.

Claims 9-20

The Examiner does not address any of Appellants' arguments regarding claims 9-20. Thus, no further comments are provided in this reply.

⁷ Page 8 of the Examiner's answer

Conclusion

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the rejections advance by the Examiner should be reversed.

Respectfully submitted, RENNER, OTTO, BOISSELLE & SKLAR, L.L.P.

By: <u>/Kenneth W. Fafrak/</u> Kenneth W. Fafrak Reg. No. 50,689

1621 Euclid Avenue, 19th Floor Cleveland, Ohio 44115 216-621-1113